PSJ17 Exh 48

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
	:	CASE NO.
THIS DOCUMENT RELATES TO ALL CASES:	:	1:17-MD-2804
	:	Hon. Dan A. Polster

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Friday, January 18, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of CAROL MARCHIONE, taken pursuant to notice, was held at Golkow Litigation Services, One Liberty Place, 1650 Market Street, Suite 5150, Philadelphia, Pennsylvania 19103, beginning at 9:31 a.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter.

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Inc. will provide a quarterly report to the FDA compiled from all data collected by the methods described under the Actiq surveillance and monitoring program interventions, see Sections 8.0 and 9.0 of the document. This report will describe and provide data and any concerns for child safety, diversion and off-label usage.

So that was -- that's the report that you were required to prepare, right?

A. That's correct.

Q. So one of those components was to provide data and concerns about off-label usage to the FDA, because they wanted to know what was happening, right?

A. Yes.

MR. CRAWFORD: Can we go off the record for a little bit? I think we might have a quarterly report, and this might be a good time to get that.

VIDEO TECHNICIAN: Going off

the record. 11:22 a.m.

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(Whereupon, a brief recess was taken.)

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VIDEO TECHNICIAN: We're back on the record at 11:34 a.m.

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(Whereupon, Teva-Marchione Exhibit-9, TEVA_MDL_A_04578988-9017, was marked for identification.)

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BY MR. CRAWFORD:

Q. Ms. Marchione, we did find a quarterly report, I believe, Exhibit-9, dated September 24th, 2003 signed by you. It's TEVA_MDL_A_04578988.

Is this a quarterly report that you referred to earlier?

A. Yes, it is.

Q. And this was prepared or compiled by you or your department, right?

A. That's correct.

Q. And submitted to the FDA, correct?

A. That's correct.

Q. And if you could, maybe take a few moments to look at it, maybe go to the first page, which is at 93.

It says, Actiq risk management program, 17th quarterly report, April 1st, 2003 to June 30th, 2003.

This was the report that was referenced in, I think, Section 10 of the RiskMAP document, right?

A. That's correct.

Q. And this is a report that you would prepare in your ordinary course of business, right?

A. That's correct.

Q. And this one, in fact, was submitted to the FDA?

A. That's correct.

Q. And I think the first page here, Page 2, actually, it says, Actiq

surveillance and monitoring programs, Sections 8 and 9, surveillance goals and activities.

And then it starts with direct patient feedback and continues through with sections that correspond to the actual RiskMAP sections, right?

A. That's correct.

Q. So I think my question was -- that you wanted to refer to it -- I think it was dealing with the 15 percent requirement in the Actiq RiskMAP, right?

A. That's my recollection.

Q. Yeah. I think that was -- just so you can pull it up next to it, that was Exhibit-7, Page 27, groups of prescribers, under off-label usage.

And I think I had asked you exactly how -- how the company interpreted and implemented this mechanism to evaluate the prescribing by these groups of physicians.

Is there anything -- and

take your time, but is there anything in the quarterly report that triggers your recollection of how the company might have interpreted and utilized and implemented that mechanism?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Just give me a minute, please.

BY MR. CRAWFORD:

Q. Take your time.

This one, actually, I think, at Page 11 and 12, seems to skip over the 9.1.2 section.

A. That's what I'm looking at.

Because we did -- oh, God. We did always have the 15 percent cutoff. There was an IMS printout that listed -- did we -- wait a second.

So in Section 8.2.1 on Page 3, under, NDC Source Prescriber audit, it states there, The data from the NDC Source Prescriber audit shows that none of the nontargeted physician specialties

exceeded 15 percent of the total prescriptions during 2Q03.

So the actual documentation, if I remember correctly, you know, was very long and -- but we would get the information and review it and put that statement.

So it's on Page 3, under 8.2.1.

Q. Right. Okay. So the corresponding section in the Actiq RiskMAP is on Page 23, under 8.2.1, IMS Xponent. That shows a different data source, NDC Source Prescriber audit.

Is that the reason why that's different than what's required by the RiskMAP?

A. This is one of those evolving operational things. And maybe the IMS Xponent wasn't available any longer. So I think they switched over to an NDC component.

Q. Do you know if the FDA ever approved that switch?

MR. DIAMANTATOS: Object to form.

Go ahead.

THE WITNESS: I doubt it. Again, we informed them every time we changed something. But, as I mentioned earlier, they -- we never got, you know, an acknowledgment letter.

We definitely sent it in writing that -- what we were changing along the way.

BY MR. CRAWFORD:

Q. Right. But there's nothing in 8.2.1 that talks about the 15 percent --

A. So I think --

Q. -- specialties. That comes under -- if you look under the RiskMAP on Page 27, that 15 percent is under 9.1.2.

And you'll agree with me that that section is omitted, 9.1.2, from the report, right?

A. I agree. And it's one of

those historical -- if you looked back in the communication logs, we probably communicated that we were now combining -- using the IMS for the Xponent.

And that's why we say here explicitly that the nontargeted physician specialties exceeded 15 percent of the total prescriptions.

And it's one of those things that you have to go back historically and look at all the FDA correspondence to figure out when that changed and why, and we explain that.

Q. But, I mean, it would have been just as easy to put it under 9.1.2 on Page 12, right after 9.1.1, talking about individual prescribers.

I mean, is there a reason why you couldn't have put it under that section, which is the logical section, because that's where 15 percent is discussed, in that section?

A. Right. And I believe -- I

can't remember exactly, but because they were both kind of looking at the same thing, I think we combined it into that.

So we could repeat it again, but -- if you looked at the progression of the reports and the communication, it would probably make a lot of sense where things were. We told them we were moving things or what we were doing.

So we were probably using the same source now to answer both things. So this came up first, and that's why we put it there.

Q. So was there ever any point in time that you, in one of these reports, reported that there were nontargeted physician specialties that did exceed 15 percent of total prescriptions?

MR. DIAMANTATOS: Objection. Form. Vague as to time.

BY MR. CRAWFORD:

Q. At any time.

A. I think there was one --

MR. DIAMANTATOS: Same objection.

THE WITNESS: -- quarter, or two. It was later in the -- it was later, you know, towards the end of the marketing or the sales.

So I don't know -- I can't exactly -- but we only exceeded it once or twice. That why I wanted you to actually see this, because we never -- I think we initially -- we can find the date -- we never exceeded it except for once or twice.

BY MR. CRAWFORD:

Q. All right. And then do you remember what nontargeted specialties exceeded 15 percent in those reports?

A. I don't remember.

Q. All right. And what is a nontargeted physician specialty?

A. I believe -- I believe somewhere down the line we communicated to the agency who -- the groups that

they -- I don't know who, I guess, commercial, identified were not prescribing for oncology.

So it could go beyond oncologists. And so whatever groups that they identified, there's a communication somewhere and why they chose those groups.

Q. All right. So just turn to Page 27 of Exhibit-7.

I'm trying to understand about the -- this is 9.1.2.

A. 27 --

Q. That would be exhibit, I'm sorry, Exhibit-7, which is the Actiq RiskMAP.

A. I'm sorry, what page?

Q. I think you might be in the quarterly report.

A. You want 27, sorry.

Q. Yes.

A. Okay.

Q. And I'm just trying to understand what you're reporting here.

So what the FDA -- or what the RiskMAP says is, If groups of physicians (such as a particular specialty) are identified as having prescribed Actiq inappropriately and these prescriptions represent potential off-label usage greater than 15 percent of total quarterly Actiq prescriptions, Cephalon will contact the appropriate professional society.

A. Right.

Q. It gives examples, American College of Surgeons, American Society of Anesthesiologists.

And then you say in your report to the FDA, under 8.2.1, Data from the NDC Source Prescriber audit show that none of the nontargeted physician specialties exceeded 15 percent of the total prescriptions during Q203.

So the nontargeted physician specialties are specialties that are not -- would not be prescribing the drug as it was indicated, right?